## **ORIGINAL PAPER**



# Mindfulness-Based Stress Reduction Intervention in Chronic Stroke: a Randomized, Controlled Pilot Study

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# Abstract

**Objectives** Mindfulness-Based Stress Reduction (MBSR) involves training in mindful meditation and has been shown to improve functioning across a range of different disorders. However, little research has focused on the use of MBSR in stroke patients, and previous MBSR studies typically have not included an active control condition to account for non-specific factors that could contribute to the observed benefits.

**Methods** We conducted a pilot study of MBSR in chronic stroke patients, comparing MBSR to an active control condition. Half of participants were randomly assigned to a standard 8-week MBSR class, and the other half of participants were assigned to an 8-week Brain Health class matched for schedule, instructor, and format. Participants were assessed pre- and post-intervention by blinded examiners on a neuropsychological battery that included primary outcome measures of psychological and cognitive functioning. Participants were also given an anonymous questionnaire following the post-intervention testing session to measure class satisfaction.

**Results** Both the MBSR and Brain Health classes were rated favorably by participants. Recruitment and retention rates were high, and methods for participant randomization and examiner blinding were successful. Class implementation in terms of execution was also successful, as rated by outside experts.

**Conclusions** This study established the feasibility of conducting MBSR and Brain Health classes in a chronic stroke population.

Trial Registration https://ClinicalTrials.gov, NCT #: 02600637

Keywords Mindfulness-based stress reduction · Stroke · Alternative medicine · Anxiety · Depression · Cognition

Approximately 800,000 people in the USA suffer a stroke every year (Go et al., 2013; Oberg et al., 2000). Many of these individuals are affected by significant neuropsychological deficits, including both emotional and cognitive changes. The reported incidence of post-stroke depression ranges from 20 to 50%, and post-stroke anxiety affects approximately 25% of stroke patients (Allan et al., 2013; Burton et al., 2013; Paolucci, 2008; Srivastava et al., 2010; Starkstein & Robinson, 1989). Even in those individuals not meeting formal criteria for major depression or anxiety, clinically significant symptoms are often present. The emotional impact of stroke greatly reduces patients' quality of life as well as their ability to benefit from rehabilitation (Ferro et al., 2009; Laures-Gore & DeFife, 2013; Robinson & Spalletta, 2010). Similarly, cognitive changes such as deficits in attention and memory are very common after stroke, posing significant barriers to activities of daily living and well-being (Dhamoon et al., 2010; Nys et al., 2006). While many patients receive rehabilitation during the acute/ sub-acute phases of stroke, fewer options exist for the treatment of persisting psychological and cognitive deficits in the chronic phase of stroke.

A growing number of studies have begun to assess the feasibility and efficacy of using alternative interventions in the treatment of psychological changes following stroke (Baylan et al., 2018; Jani et al., 2018; Lazaridou et al., 2013;

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Xiaoyu Wang et al., 2020; Xu Wang et al., 2019). These approaches include relaxation/stress-reduction programs such as Mindfulness-Based Stress Reduction (MBSR; Alsubaie et al., 2017; Carmody & Baer, 2008; Kabat-Zinn, 1990). MBSR and related interventions involve training individuals to use mindfulness techniques, which involve focusing attention on breathing and other bodily sensations. These techniques have been used to reduce stress and improve coping and recovery in a variety of different patient groups (Hofer et al., 2014; Jha et al., 2017; Joo et al., 2010; Marshall et al., 2014).

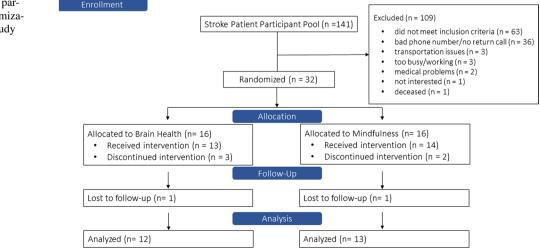
To date, only a few studies have evaluated the use of MBSR in brain-injured individuals (Abbott et al., 2014; Fjorback et al., 2011), and just one of these studies was a randomized controlled trial that involved stroke patients (Johansson et al., 2012). In that study, MBSR was delivered to a heterogeneous group of 15 individuals with a history of either stroke or traumatic brain injury. Johansson et al. found that MBSR was associated with improvements in mental fatigue and cognitive performance, relative to controls. However, the control group in the study was passive (i.e., received no intervention), similar to many other studies of MBSR. Without an active control group, it is difficult to know whether gains in psychological and cognitive functioning are specific to the MBSR intervention or are instead due to other non-specific factors, such as increased social stimulation or the group dynamic. Additional issues in previous MBSR studies include the lack of long-term follow-up to evaluate lasting effects of MBSR, as well as the use of non-blinded examiners which can bias test administration and interpretation (Fjorback et al., 2011).

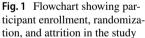
The current study involved a randomized pilot trial of MBSR in chronic stroke that included a well-matched active control intervention, blinded examiners, and 3-month follow-up testing. The main aim of this pilot study was to evaluate the feasibility of conducting MBSR and Brain Health classes in a chronic stroke population, to inform future studies conducting larger, randomized clinical trials (Arain et al., 2010; Leon et al., 2011; Thabane et al., 2010; Whitehead et al., 2014). Our prediction for the current study was that both MBSR and Brain Health classes would be feasible with respect to implementation, practicality, integration, and acceptability.

# Methods

#### Participants

Participants (n=32) were recruited from a stroke database at VA Northern California Health Care System and included both Veterans and non-Veterans. Of the 141 participants in the active participant pool, 63 were excluded because they did not meet study criteria, and 36 could not be contacted (e.g., due to bad phone numbers, no return call; see Fig 1 for enrollment flowchart). Participants interested in volunteering for the study also had to meet eligibility criteria. Inclusion criteria were as follows: history of a single, chronic right or left hemisphere stroke ( $\geq 3$  months post-onset so that residual symptoms had stabilized), age between 20 and 80, and native English proficiency. Exclusion criteria were as follows: Mini-Mental State Examination score <19 (which would suggest moderate-severe cognitive impairment, a contraindication for effectively participating in the MBSR intervention; Johansson et al., 2012); pre-morbid neurologic history (e.g., dementia, Parkinson's disease); history of severe psychiatric disorder (e.g., schizophrenia, bipolar disorder); recent substance abuse/dependence disorder (within 1 year); acutely suicidal; concurrent involvement in another rehabilitation program; moderate-severe aphasia; and significant visual or hearing disabilities that would preclude effective participation.





Medical history, including pre-morbid neurologic and psychiatric history, was assessed during the initial interview session. A review of participants' available medical records was also conducted. Medications were not an exclusionary factor for participation but were recorded. Participants were paid at the rate of \$20/h for the testing sessions; they were not paid for their participation in the 8-week classes. In terms of ethnicity, the first round of the MBSR class included one Asian American participant and seven European American participants, while the second round of MBSR included one Asian American participant, two African American participants, and five European American participants. The first round of the Brain Health class included eight European American participants, while the second round of Brain Health included one African American participant and seven European American participants.

## **Procedures**

After agreeing to voluntarily participate in the study and completing informed consent, half of the participants were randomly assigned to the MBSR intervention, and half were randomly assigned to the Brain Health control intervention. Randomization assignments were generated by the study statistician with age and gender as blocking factors (male vs. female and < 65 vs.  $\geq$  65). Random assignments were placed in sealed numbered envelopes by the statistician, marked with the combined factor group, and opened in sequence by study staff as participants were recruited.

Several procedures were implemented to maintain blinding in this randomized trial. It was not possible to have a true double-blind trial since participants were informed about the course content during the first session of the class. Rather, we minimized participant bias in two ways. First, participants were told at the outset of the study and on the consent form that they were being randomized to one of two Brain Health and Wellness classes. To reduce participant demand characteristics, they were told (truthfully) that both types of classes have been taught on the VA campus and that this study aimed to compare their usefulness. Second, we instructed participants not to speak to participants in the other class about the course material (in case they knew someone in the other class). To minimize potential examiner bias, the examiners administering the neuropsychological tests were neuropsychologists who were not part of the research team that handled study procedures and recruitment. Also, participants were instructed and reminded on multiple occasions not to discuss their class with the examiner. We also checked for potential bias across participants and examiners (see "Measures" below). All participants were informed what the other class covered in a debrief letter after the 3-month follow-up was complete.

#### Assessment

Participants were assessed at three time points: (1) within 2 weeks prior to the intervention (pre-testing), (2) within 2 weeks following the intervention (post-testing), and (3) 3 months following the intervention (follow-up testing). All three time points included a questionnaire packet measuring the preliminary outcomes (see "Measures" below). A full neuropsychological battery was administered during the first and second timepoints by a trained neuropsychologist who was blind to the participants' intervention condition (MBSR or Brain Health). Four different neuropsychologists conducted assessments, and the same examiner always re-tested the same participants pre- and post-testing. An anonymous questionnaire assessing study acceptability was administered at the second timepoint (after participants completed the intervention). To minimize bias, each participant completed this questionnaire individually in a private room away from the class instructor, examiner, and other participants, before placing the questionnaire into a large envelope with other questionnaires to ensure anonymity.

#### **Treatment Interventions**

Participants took part in one of two treatment interventions, MBSR or a Brain Health education class. There were two rounds of classes during the study, for a total of two MBSR classes and two Brain Health control classes (see Tables 1 and 2 for weekly topics and descriptions). The MBSR class was a standard University of Massachusetts MBSR course, which includes an introductory session followed by 8 weeks of classes (Kabat-Zinn, 1990). The class was led by a trained and certified MBSR instructor with over 10 years of experience. The MBSR class met once per week for 2.5 h, with a day-long retreat in the 6<sup>th</sup> week of the 8-week program. Participants were instructed in mindfulness practice in the form of sitting meditation, body awareness, yoga, mindful movement, and informal mindfulness practices of daily life (e.g., eating, communicating, working, coping). The day-long retreat included a review of class material, more lengthy meditation, and yoga practice, as well as a group lunch. There was a 15-min break midway during each regular class, and the retreat included an hour break for lunch and two additional 15-min breaks.

Between MBSR classes, participants enhanced learning by practicing at home with meditation CDs, homework assignments, and readings from the course materials and manual. Home practice was tracked with homework logs, on which participants recorded the number of hours engaged in practice at home. Homework logs were checked and collected by study staff each week. The MBSR class conformed to the standard University of Massachusetts 8-week MBSR curriculum with respect to class implementation, meditation

#### Table 1 Weekly topics and material covered in MBSR class

	Theme	Lecture, practice, and discussion topics
Introduction	Introduction to MBSR	Orientation, introductions, course overview
Session 1	Mindfulness overview	Theory and evidence of mind-body medicine, discussion of mindfulness principles
Session 2	Perceptions	Body-scan practice, perceiving/responding to stressful situations
Session 3	Being present in the moment	Mindful hatha yoga, sitting and walking meditation, share insights into experience with formal practice
Session 4	Coping with stress	Responding versus reacting to stress, ways to reduce stress
Session 5	Mental reactivity	Mindful consumption, informed awareness versus habitual behavior
Retreat	Day of mindfulness	Establish use of MBSR skills across multiple life situations
Session 6	Interpersonal mindfulness	Mindful communication, applying awareness with difficult communication and when strong emotions are present
Session 7	Embracing change	How to integrate mindfulness into daily life; walking meditation, mindfulness and self-reflec- tion in decision-making
Session 8	Integrating practice into daily life	Review of all course material, how to carry momentum forward, resources to pursue mindful- ness on one's own

Table 2 Weekly topics and material covered in Brain Health class

	Topic	Lecture material
Introduction	Basic Brain Anatomy	Course overview, basic brain facts, four lobes and functions, additional cortical and subcortical regions and functions
Session 1	Neuroplasticity	Parts of the neuron, Hebbian Principles, synaptic pruning, relevance of plasticity to learning and memory
Session 2	Movement, vision, language	Brain regions underlying functional systems, dissociable functions within systems
Session 3	Memory, forgetting	Brain regions underlying memory, strategies to improve memory; exercise and nutrition for improved memory; types of memory
Session 4	Attention, executive functioning	Different types of attention and executive functioning, associated brain regions
Session 5	Sleep, stress	Stages of sleep, Epworth Sleepiness Scale, brain/body regions underlying stress response
Retreat	Diet, physical activity	Nutritious eating, healthy brain foods, effect of exercise on brain
Session 6	Aging	Physical changes in the brain with aging, lifestyle factors
Session 7	Emotions	Different emotions and emotional styles, associated brain regions
Session 8	Social bonds	Mirror neurons, autism, associated brain regions

times, and homework, etc. The MBSR weekly themes were explored through a number of different meditations practices of 40 - 45 min in length, done both in class as a group and assigned as a daily home practice. The weekly themes and associated meditations were assigned according to the standard MBSR curriculum.

The other half of the study participants were assigned to an active control intervention, a Brain Health education class. This class was matched to the MBSR intervention with respect to the number of class hours (2.5 h/week), schedule (8-week class plus an introductory session and a day-long retreat), class size (7–10 participants), instructor, and homework. The Brain Health class was a modification of an existing VA education class for brain-injured individuals taught on the VA campus. The class provided background and education about brain-behavior relationships and discussed how brain injuries can disrupt various aspects of cognition, such as memory and attention. There were also units on nutrition, sleep, and strategies for successful aging (e.g., healthy eating, sleep hygiene). Each class included a combination of lecture with slides and videos (~1.5 h) plus group discussion (~.75 h), during which participants had opportunities to discuss their experience with stroke in relation to the different week's topics. Like the MBSR class, every class had a 15-min break, and the retreat day included an hour break for lunch and two additional 15-min breaks. Homework in the Brain Health class included readings and questions related to each week's topic.

To control for the yoga/movement portion of the MBSR class, the Brain Health class also included simple chair exercises, such as stretching and reaching. The Brain Health retreat class included a review of class topics, video documentaries on brain topics, and a group lunch. Thus, the Brain Health class matched the MBSR intervention for critical process elements such as clinician interaction, social interaction with the group, movement, schedule, and homework activities, without the inclusion of a meditative/mindfulness component, which is hypothesized to be the critical factor for improving outcome with MBSR (Kabat-Zinn, 1990). In both classes, participants were told at the outset that they could not miss more than three class sessions total, or they would be dropped from the study.

The same instructor taught both the MBSR and Brain Health classes, to avoid the variability that could be introduced with different instructors. One instructor taught the first round of MBSR and Brain Health classes, and another instructor taught the second round. Because the same instructor taught both classes, there were some concerns about cross-contamination (e.g., discussion of meditation in the Brain Health class). The class instructor was aware of this potential issue and worked to consciously avoid crosscontamination by, for example, redirecting discussion if a student in the Brain Health class mentioned topics covered in the MBSR class, such as meditation. As a check of crosscontamination, participants were queried post-intervention with a short questionnaire about their prior knowledge of class topics and how much they learned during the class about topics such as mindfulness (which should only have been endorsed by participants in the MBSR class) and brain-behavior relationships (which should only have been endorsed by participants in the Brain Health class).

## Measures

Feasibility in the current pilot study was defined according to the areas of focus described by Bowen et al. (2009): (1) implementation—how well the interventions were executed, including recruitment, randomization, and blinding; (2) practicality—ease and efficiency of delivering and participating in the interventions, including attendance, retention, and participant engagement; (3) integration—the degree to which participants used the skills in daily life; (4) acceptability—participant satisfaction and reaction to the program; and (5) preliminary outcomes—test change scores and standard effect sizes on outcome measures.

#### Implementation

To evaluate recruitment feasibility, we calculated the percentage of participants who agreed to take part in the study, relative to the total number of people we contacted. To assess our randomization/stratification procedures, we compared the two groups of participants with respect to demographics. To evaluate blinding procedures, we tested whether the examiners were at chance levels when asked to guess which class each participant had taken, and we queried participants as to what they thought the other class covered. For successful course implementation, the course instructor was rated by two experts with extensive familiarity with the classes, based on 20-min video clips of the two classes. Raters provided scores on a scale from 1 (no adherence) to 5 (high adherence), with higher numbers indicating better adherence to the course manuals.

### Practicality

Retention was based on the number of recruited participants who completed the program. Participant attendance was recorded by the course instructor, while engagement was measured through (a) the number of hours participants spent completing homework (self-reported through a homework log), and (b) instructor-provided ratings of class engagement and comprehension using a scale of 1–10, with higher scores indicating greater engagement or comprehension/retention.

# Integration and Acceptability

Participants anonymously completed a nine-item questionnaire created by the authors (see Table 3). As a measure of integration, participants answered a series of questions on a scale of 1 (very unlikely) to 5 (very likely), such as "*How likely are you to continue to study and practice the skills you learned in this class*?" As a measure of acceptability, participants provided ratings on a series of questions, such as "*How satisfied were you with this class*?" on a scale of 1 (very unsatisfied) to 5 (very satisfied); "*Overall, how do you cope with stress now, compared to before the class*?" on a scale of 1 (much worse) to 5 (much better); and "*Have there been any specific positive changes in your medical condition*?" (1= yes, 0=no).

## Cognitive

The primary cognitive outcome measure was the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS; Randolph, 1998). The RBANS tests a range of cognitive functions and was developed for the purpose of testing participants at different time points with multiple, matched versions of the measure that test a range of cognitive functions. Specifically, the RBANS assessment has multiple matched versions (RBANS-A, B, C, etc.), so that repeat testing is similar but not identical, and the scoring accounts for any improvement in scores at follow-up testing due to learning effects and participants' simply being more familiar with the tests. The RBANS includes 12 subtests and yields index scores for five cognitive domains: attention, immediate memory, long-term memory, language, and visuospatial abilities. In the current study, the two domains of primary interest were attention and immediate memory (i.e., working memory), due to the putative effects of MBSR on enhancing focus and reducing distractibility (Tang et al., 2015). Matched versions of RBANS-A and RBANS-B were Table 3 Anonymous post-intervention questionnaire items with average scores and standard deviations

Questionnaire items	MBSR	Brain Health
1. Overall, how do you cope with stress now, compared to before the class?	4.1 (0.7)	3.5 (0.5)
2. Overall, how would you rate your thinking skills, compared to before the class?	3.7 (0.8)	3.8 (0.6)
3. Overall, how is your health now, compared to before the class?	3.5 (0.9)	3.5 (0.7)
4. Overall, how is your attitude towards your health now, compared to before the class?	3.9 (0.6)	3.9 (0.7)
5. How satisfied were you with this class?	4.4 (0.9)	4.3 (0.9)
6. How satisfied were you with the class instructor?	4.4 (0.7)	3.9 (1.0)
7. How likely would you be to recommend this class to a friend?	4.2 (1.1)	4.3 (1.1)
8. How likely are you to continue to study and practice the skills you learned in this class?	4.1 (1.1)	4.1 (0.9)
9. Was the course schedule (one day a week plus an all-day retreat) easy to fit in your schedule?	4.0 (1.2)	4.3 (0.9)
10. Have there been any specific positive changes in your medical condition? If so, please describe.	50%-yes	14%-yes
11. Have you made any changes in your lifestyle? If so, please describe.	71%-yes	27%-yes
12. What was your most significant insight during the class?	n/a	n/a
13. Please write a few sentences about the course instructor.	n/a	n/a
14. Please write any comments or suggestions for the class.	n/a	n/a

Participants were asked to rate items 1–9 on a scale from 1 to 5, where 5 was better/more likely. Items 10–14 were open-ended questions. *n/a* not applicable

administered by trained neuropsychologists during the preand post-testing timepoints, respectively. The RBANS was not repeated at 3 months, since it requires in-person testing, and participants completed the 3-month follow-up via mail.

## Health and Well-being

The Geriatric Depression Scale-15 (GDS; Sheikh & Yesavage, 1986) and the State-Trait Anxiety Inventory (STAI; Spielberger et al., 1983) were administered to measure subjective symptoms of depression and anxiety, respectively. The GDS was chosen as a measure of depressive symptoms due to the older age of the sample. Form Y-1 of the STAI was used for the current study, as it asks about current anxiety symptoms (i.e., current state). Both measures have been shown to have strong reliability and validity (Barnes et al., 2002; Chiesi et al., 2017). Within our sample, internal reliability for the GDS ( $\alpha = .85$ ) and STAI ( $\alpha = .95$ ) ranged from good to excellent.

Participants also completed the RAND 36-Item Short Form Health Survey (RAND SF-36 v. 1.0), which asked participants to rate current functioning across a variety of health domains. This measure provided a means of evaluating improvements in daily functioning by measuring change scores from pre- to post-intervention, as well as from postintervention to the 3-month follow-up. The RAND SF-36 was scored according to the standard instructions and included eight subscales: Physical Functioning, Limitations due to Physical Problems, Limitations due to Emotional Problems, Energy/Fatigue, Emotional Well-being, Social Functioning, Pain, and General Health. Items are scored such that higher values indicate better health outcomes. Subscale reliabilities ranged from adequate to excellent ( $\alpha$ s: physical functioning= .93, role limitations due to physical health= .88, role limitations due to emotional problems = .83, energy = .89, emotional well-being = .84, social functioning = .90, pain = .84, general health = .77).

A series of secondary outcome measures were also collected, as they have been used previously to measure changes in subjective experience in response to mindfulness interventions. These included the Cognitive Failures Questionnaire (Broadbent et al., 1982), the Satisfaction with Life Scale (Diener et al., 1985), and the Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003). The Cognitive Failures Questionnaire is a series of 25 items (e.g., Do you find you forget people's names?) that ask participants to rate how often they make minor mistakes on a scale from 0 (never) to 4 (very often). The Satisfaction with Life Scale is a series of 5 items (e.g., I am satisfied with my life) on which participants rate their sense of satisfaction with their lives on a scale from 1 (strongly disagree) to 7 (strongly agree). The Mindful Attention Awareness Scale is a series of 15 items that queries everyday experiences of awareness (e.g., I find it difficult to stay focused on what's happening in the present). Participants rate each item on a scale from 1 (almost always) to 6 (almost never). Reliability for the scales ranged from good to excellent ( $\alpha$ s: Cognitive Failures Questionnaire = .88, Satisfaction with Life Scale = .92, MAAS = .95).

## Data Analyses

Descriptive statistics are presented below for the different areas of feasibility (Bowen et al., 2009). Standard effect sizes (SEs) are provided in addition to descriptive statistics to assess preliminary effectiveness on the primary outcome measures (Fendel et al., 2020). Significance testing was not conducted due to the small sample sizes in this study, which was designed primarily to serve as a pilot-feasibility study.

# Results

## Implementation

Of the 42 individuals who were contacted, 76% (32 out of 42) were interested in participating (see Fig 1). This rate surpassed the feasibility criterion of 70% (Thabane et al., 2010). Implementation based on expert rating of instructor adherence to class manuals was also good, with the instructors receiving an average of 4.5 out of 5 for the Brain Health class and 5.0 out of 5 for the MBSR class. Random assignment of participants to the two different treatment interventions was successfully executed with a blinded procedure that controlled for demographic variables. The MBSR and Brain Health groups were matched on two blocked factors: Gender (both groups had five female participants) and age (Ms = 64.8 and 67.3, SDs = 12.0 and 9.5, respectively).Other recorded demographics included years of education (Ms = 16.1 and 15.4, SDs = 2.2 and 2.4, respectively) and months post-stroke (Ms = 125.8 and 138.1, SDs = 98.4 and 96.1, respectively).

The procedures for examiner blinding were also successful. No examiners reported instances of being informed of a participant's class membership, either by a participant or by a member of the research team. For participants, there was no indication from the post-testing questionnaires that any participant had knowledge of the content of the other class. Nor was there any indication on the questionnaires that participants in either class felt as if they were in a control condition.

## Practicality

Of the 32 individuals who were interested in participating and randomized to one of the two interventions, 14 out of 16 participants completed the MBSR class, and 13 out of 16 participants completed the Brain Health class. Retention rate was thus high for a study of such long duration (Cramer et al., 2016). Four of the five participants who withdrew did so due to medical issues (n = 3) or transportation issues (n= 1). The fifth participant who withdrew was an older male Veteran in the MBSR class who withdrew due to lack of interest. Of the 27 individuals who completed the 8-week interventions, 25 completed the 3-month follow-up (one participant from each class failed to return their 3-month follow-up questionnaires).

Participant engagement as measured by attendance and engagement with homework material was also very high for both classes. Attendance was 93% in the MBSR class and 94% in the Brain Health class. No participants missed more than three classes. For the number of hours that participants spent doing home practice, the average number of hours of practice/homework completed by participants in the first round of the MBSR class (e.g., meditation, yoga, body scan) was 3.1 h/week (SD = 1.6), while the average number of hours of homework completed in the first round of the Brain Health class (e.g., reading, self-tests) was 1.2 h/ week (SD = 1.2). Due to this discrepancy between classes, additional readings were included in the second round of the Brain Health class. This adjustment resulted in an increase in the average number of hours in the Brain Health class, but there was still a numerical discrepancy between the classes with a considerable amount of variability across participants (MBSR M: 3.2 h, SD = 1.6 and Brain Health M: 2.2, SD =2.4). Four participants in the MBSR class and two participants in the Brain Health class did not turn in their homework logs for at least one of the 8 weeks.

Last, practicality was measured by instructor ratings of each participant in the class. In the MBSR class, instructor ratings for class engagement averaged 7.9 out of 10, and ratings of understanding class material averaged 8.1 out of 10. In the Brain Health class, instructor ratings of class engagement averaged 8.5 out of 10, and ratings of understanding class material averaged 8.2 out of 10.

## Integration and Acceptability

On the anonymous questionnaire, 71% of MBSR participants stated that they had made changes to their lifestyle versus only 27% of the Brain Health participants. Both classes averaged 4.1 out of 5 (with 5 indicating a greater likelihood) when reporting how likely they were to continue to study and practice the skills they learned in class.

Overall, both the MBSR and Brain Health classes were rated quite highly (see Table 3). The class satisfaction rating was 4.4 out of 5 for the MBSR class and 4.3 out of 5 for the Brain Health class (with higher scores indicating greater satisfaction). The class instructor rating was numerically higher for the MBSR class (4.4 out of 5) relative to the Brain Health class (3.9 out of 5). Interestingly, the questionnaire item that queried how well participants coped with stress after the class revealed the largest numerical difference between the MBSR and Brain Health classes, with an average rating of 4.1 for the MBSR class and 3.5 for the Brain Health class (with higher scores reflecting better coping). On the two yes/no questions, more MBSR participants (50%) endorsed positive changes in their medical conditions relative to Brain Health participants (14%). The additional open-ended questions (e.g., What was your most significant insight during the class?) also elicited many positive responses from the MBSR class (see Table 4 for sample responses). Two Table 4 Responses to open-ended items on the anonymous questionnaire from MBSR participants

"I found it really interesting that I didn't hear any other noise. It was though we had gone into this collective experience, beautiful and tender. I'm just going to get more relaxed every time I come over here. I've never experienced this here before."

"My mind is getting right!"

"I had a really relaxing feeling all day. Even when I got bad news, I was able to put it aside."

"I get to relax like I don't have a chance to very often. I like the fact that I'm tired instead of being upset about being tired."

"I'm watching how I respond to her death [recent loss of a family member]. I know this is a real opportunity for me to take care of myself."

 Table 5
 Mean change scores, standard deviations, and standard effect sizes (SE) on the RBANS from pre- to post-intervention

Outcome measure	MBSR		Brain Health		
	M Change (SD)	SE	M Change (SD)	SE	
RBANS Total	7.7 (8.4)	0.9	3.1 (5.7)	0.5	
Immediate memory	7.8 (11.3)	0.7	2.2 (5.5)	0.4	
Attention	5.2 (11.7)	0.4	5.7 (8.6)	0.7	

participants (both in the Brain Health class) failed to respond to a small number of items on their questionnaires.

## **Outcome Measures**

Mean change scores for outcome measures from pre- to postintervention are shown in Tables 5, 6, 7, and 8. Standard effect sizes are also included for all preliminary outcome measures.

# Discussion

The current pilot study demonstrated the feasibility of conducting both MBSR and Brain Health education classes in a sample of chronic stroke patients with respect to implementation, practicality, acceptability, and integration (Bowen et al., 2009). These results suggest that interventions like MBSR can be implemented in the chronic phase of stroke recovery when rehabilitative options are typically limited. MBSR also provides the possibility of reducing the risk for subsequent strokes and other vascular events, thereby serving as a potentially preventative health measure (Abbott et al., 2014; Krittanawong et al., 2020; Lazaridou et al., 2013).

Implementation in the current pilot study was evaluated in several ways. First, recruitment efforts were very successful, with over 75% of individuals contacted agreeing to participate. Random assignment to the MBSR and Brain Health classes was also successful, resulting in wellmatched groups of participants based on age and gender. Third, expert reviewers rated videotape samples of the class instructors for adherence to the class manuals, and these samples were rated very highly. Last, examiners conducting the pre- and post-assessments were successfully blinded, as

Table 6Mean change scores(SDs) and standard effect sizes		MBSR				Brain Health			
(SEs) on the GDS and STAI from pre- to post-intervention and from post-intervention to		Pre-Tx to Post- Tx Change <i>M</i> (SD)	SE	Post-Tx to 3-months Change <i>M</i> (SD)	SE	Pre-Tx to Post- Tx Change <i>M</i> (SD)	SE	Post-Tx to 3-months Change <i>M</i> (SD)	SE
the 3-month follow-up	GDS	-0.3 (2.5)	-0.1	0.5 (4.2)	0.1	-1.5 (2.0)	-0.8	1.4 (2.0)	0.7
	STAI	0.6 (4.7)	0.1	6.2 (8.9)	0.7	-2.3 (7.2)	-0.3	3.1 (7.5)	0.4

Tx = treatment

Table 7 Mean change scores and standard deviations on secondary outcome measures from pre- to post-treatment

	MBSR		Brain Health	
	Pre-Tx to Post-Tx	Post-Tx to 3 months	Pre-Tx to Post-Tx	Post-Tx to 3 months
Cognitive Failures Questionnaire	1.7 (7.6)	2.5 (9.5)	-3.4 (7.6)	1.2 (14.0)
Mindfulness Attention Awareness Scale	-1.6 (12.8)	-0.5 (9.5)	1.8 (12.2)	-4.4 (26.2)
Satisfaction with Life Scale	2.5 (5.3)	-1.5 (4.1)	-1.0 (4.1)	0.5 (8.4)

Tx = treatment. All scores presented are *M* Change (*SD*)

	MBSR		Brain Health		
	Pre-Tx to Post-Tx	Post-Tx to 3 months	Pre-Tx to Post-Tx	Post-Tx to 3 months	
Physical Functioning	0.4 (13.9)	2.3 (8.5)	9.2 (15.4)	-12.7 (24.6)	
Limitations-Physical Problems	17.9 (33.1)	-16.7 (54.7)	11.5 (36.3)	-3.8 (47.7)	
Limitations-Emotional Problems	-4.8 (45.0)	-22.2 (38.5)	7.7 (38.9)	-2.8 (38.8)	
Energy/Fatigue	4.3 (14.0)	-2.9 (18.1)	5.8 (13.2)	-2.9 (17.1)	
Emotional Well-being	0.6 (12.1)	-12.3 (15.4)	2.8 (18.2)	-9.3 (30.5)	
Social Functioning	-1.8 (10.8)	-9.4 (17)	9.6 (18.5)	-14.8 (33.9)	
Pain	-2.9 (14.9)	-2.1 (11.6)	3.6 (12.9)	-5.0 (13.5)	
General Health	0 (11.3)	-5.4 (16.6)	4.2 (15.9)	-11.2 (24.6)	

Table 8 Mean change scores and standard deviations on the Rand SF36 Symptom Inventory for MBSR and Brain Health classes

Tx = treatment. All scores presented are *M* Change (*SD*)

evidenced by at-chance performance on forced-choice tests on which examiners guessed participants' class assignment (MBSR or Brain Health).

With respect to practicality, high participant retention rates were reported: Only five participants dropped out after the interventions had started, mostly due to medical and transportation issues. Participants in both the MBSR and Brain Health groups appeared motivated to meet every week, as evidenced by very high attendance rates and an average of 1–3 h spent in homework practice per week. Last, the class instructor ratings of participants with respect to class engagement and understanding were also quite high.

Acceptability and integration were measured in part by an anonymous class survey that included both scaled and openended items. Participants in both classes reported high satisfaction ratings with respect to the class overall. Participants' satisfaction ratings for the Brain Health control intervention were better than expected, perhaps because the educational class provided some subjective benefit due to the weekly group interactions, positive social stimulation, and opportunity for learning. Participants in the Brain Health class often related their learning to their experience of recovery from their stroke, and there appeared to be a dynamic social bond developed through this experience.

With respect to integration, a large percentage of MBSR participants (71%) participants endorsed the statement that they had made changes to their lifestyle as a result of the class (versus only 27% of Brain Health participants). Participants in both classes responded at a high rate that they were likely to continue to study and practice the skills that they had learned during the study.

Preliminary outcome data in the current study were presented with respect to mean change scores and standard effect sizes on primary outcome measures for the MBSR and Brain Health classes. Some of these change scores exceeded a clinically significant change (Duff et al., 2004; Phillips et al., 2015), suggesting that a larger randomized clinical trial is warranted to statistically evaluate these effects. The sample size in this pilot study was not sufficiently large to provide appropriate levels of statistical power to evaluate treatment efficacy.

Several procedures were implemented in the current pilot study to reduce examiner and participant bias, which were successful. It was not possible to keep participants truly blinded, as the content of their class interventions was apparent on the first day of participation, but bias/expectations were minimized in a number of ways. The consent form included careful wording to describe the classes without indicating predictions/expectations about benefits from one intervention over the other. Also, the instructor's introductory remarks emphasized that both classes had potential benefit, downplaying any sense of an experimental versus control condition. There was no indication from the posttesting questionnaires that participants in the Brain Health class felt they were in a control condition. To reduce possible examiner bias, examiners were outside clinicians who were not part of the immediate research team, and participants were repeatedly reminded not to discuss their class with the examiner. As an indication of the success of these blinding procedures, the examiners were given a forced-choice test as to participants' class assignment, and their guesses were at chance levels.

Participants gave high satisfaction ratings for both classes, but there were distinct differences in the content and approach of the MBSR versus Brain Health class. The Brain Health class focused on scientific topics and findings, rather than guiding themes. In the Brain Health class, discussion of the science topics was encouraged by asking participants to consider things like their experience with changes in their vision, balance, etc., associated with their stroke. The Brain Health class also discussed healthy behavior (e.g., nutrition, sleep hygiene), but participants did not explore or reflect on these behaviors outside of class. Mindfulness practice in the MBSR class included a process of discussion and reflection based on self-awareness practices and inquiry, whereas the Brain Health class stayed focused on the scientific

and practical aspects of brain health. The MBSR curriculum included large and small group discussions at specific junctures in the class as a way of highlighting and further exploring the content and participant experiences. This discussion fosters self-reflection, self-inquiry, and a deepening and evolving exploration of mindfulness on a personal level, more than as a concept. A process of mindful self-reflection and contemplation is a critical component of MBSR, but it is not discussed at all in the Brain Health class. In MBSR, an example of an insight was when a partially paralyzed participant realized she could feel parts of her body where she thought there was no sensation, "I had forgotten I could feel that!" Other insights often came directly through reflections on their growing understanding of mindfulness outside of class, like how they experienced their relationships differently after meditating. One man wondered about how his golf game had mysteriously improved and he reflected on the ways his growing more mindful might have bearing on that.

In the current study, each class generally included 7-10 participants, which is less than the typical size of an MBSR class with healthy individuals, since stroke patients were expected to need more attention and time to respond during discussions. Based on experience gained from the pilot study, this class size worked well and allowed participants to be fully engaged, while also allowing for breakouts into smaller group discussions.

This randomized pilot study established the feasibility of MBSR in a stroke population, while also revealing issues that future studies should consider when conducting a MBSR protocol in a chronic stroke population. First, questionnaires and homework logs would benefit from being digitized, as this ensures that all data are collected without omissions. Second, the amount of homework in the active control arm should be increased to be comparable to the MBSR class, for example by assigning additional readings and videos. For stroke participants in particular, videos may be less taxing than simply adding a lot more reading for homework. Last, based on comments provided by the participants, the length of the all-day retreats may also be taxing for stroke patients and may likely need to be shortened from 8 to 4 h.

#### **Limitations and Future Research**

One limitation in the current pilot study is that it excluded stroke patients with moderate to severe language and cognitive impairments, in order to ensure comprehension of class material and participation in class discussions. In future work, it will be important to explore the possibility of modifying the standard MBSR protocol to make it appropriate for individuals with aphasia and other related neuropsychological disorders, so that a larger number of patients can potentially benefit from this type of intervention (see Xu Wang et al., 2019). Also, the current study excluded stroke patients who were less than 3 months post-stroke, so that symptoms were stabilized and would not interfere with participation. In the actual sample, participants' chronicity ranged from 17 to 331 months post-stroke with an average of 230 months post-stroke, which makes it very unlikely that natural recovery processes can account for any observed changes in test scores. It is important to evaluate the usefulness of MBSR in the chronic phase of stroke, when individuals are less likely to have treatment/rehabilitation options that are typical of the acute/sub-acute phase. It will be of interest in future studies to consider whether MBSR and similar interventions can be successfully implemented during more acute phases, to determine whether early stroke recovery can be augmented. Using time post-stroke as a covariate in analyses can help identify any interactions between treatment effects and stroke chronicity.

The current study was limited by a lack of diversity in the participant sample, with an over-representation of men and European-Americans. In future studies, it will be important to emphasize outreach to specialty clinics to ensure a diverse population that better reflects regional demographics. Additionally, our preliminary findings rely on many participants' subjective reports as measures of integration and acceptability, which can be skewed due to issues such as common methods bias or social desirability (Podsakoff et al., 2003). We worked to address these issues in multiple ways by (1) providing objective measures of cognition, (2) obtaining measures from different sources when possible (e.g., both participant-rated and instructor-rated feasibility scores), and (3) obtaining anonymous measures of participant-rated feasibility measures to reduce social desirability biases.

While the goal of the present study was to provide a robust test of MBSR relative to an active control group, future research may benefit from having a third study arm without any intervention to better understand how the benefits of MBSR and an active control class compare to a pure baseline. Additionally, given that stroke participants often have well-defined lesions, it may also be important to explore the possible impact that stroke size and location have on outcomes following MBSR by analyzing participants' MRI scans with modern lesion-symptom mapping tools (Ivanova et al., 2021). Such information could help clinicians identify participants a priori who may be more likely to benefit from treatment, thus further improving the effectiveness of this seemingly simple yet potentially powerful intervention.

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Author Contribution JB designed and oversaw the execution of the study, assisted with data analysis, and was the main author of the paper; KS collaborated on the design and execution of the study, as well as assisted with data management and data analysis; SL assisted with data management, data analysis, and manuscript preparation; TH assisted with data analysis; DD taught the class interventions and assisted with design and execution of the study; JM assisted with data collection and interpretation; BC assisted with design and execution of the study; SP assisted with data collection and management; JC assisted with data management and manuscript preparation; and MC assisted with the design of the study and data interpretation. All the authors reviewed and approved the final version of the manuscript for submission.

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**Data Availability** The data presented in this manuscript are not readily available due to Department of Veteran Affairs privacy regulations. Requests to access the datasets should be directed to JB at juliana. baldo@va.gov.

## Declarations

**Ethics Approval** This study was approved by the VA Northern California Health Care System Institutional Review Board, and all study procedures were conducted in concordance with the 1964 Helsinki Declaration for the protection of human subjects.

Informed Consent All participants provided written informed consents.

Conflict of Interest The authors declare no competing interests.

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